

DEFINITIVE RESULTS OF THE SICM MULTICENTER STUDY ON TENDON ADHESIONS IN ZONE II OF THE HAND

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Study Group on post-traumatic adhesion pathology of tendons and peripheral nerves (*)

SUMMARY

Purpose: *Injuries of hand involving zone II are burdened by a significant number of treatment failures due to the development of adhesions that prevent normal gliding of tendons. Surgical adhesions are the result of the physiological process of tendon healing during the first 14 days following surgery. Due to the high frequency of hand traumas and the poor results of surgical treatment, numerous studies have been carried out on various anti-adhesion strategies, although no definitive solution has been found.* **Methods:** *This was a multicenter, controlled, and randomized study performed under the auspices of the S.I.C.M.. Thirteen centers were involved in the study and a minimum of 4 patients for each center; patients were randomized using the sealed-envelope technique into two groups: the Hyaloglide-treated group and a control group. A total of 52 patients were enlisted.* **Results:** *Our results show, the good efficacy of the device tested in the prevention of surgical adhesions due to tenolysis in zone II of the hand, and its tolerability.* **Conclusion:** *Based on the homogeneity of the results obtained, we propose a treatment protocol based on the efficacy of the device tested.* Riv Chir Mano 2006; 3: 319-323

KEY WORDS

Tenolysis, adhesions, zone II

INTRODUCTION

Hand flexor tendons of the palm can be divided into eight different topographical zones. This classification allows one to define the best surgical pro-

cedures and rehabilitation protocols that are most appropriate for each zone. For our purposes, the classification of the International Federation of the Society of Hand Surgery (currently IFSSH) has been adopted in substitution of that proposed by

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Verdan and Michon in 1961 (1). According to this classification, zone II, sometimes referred to as “no man’s land”, extends from the distal palmar fold to the second phalanx where the superficial flexor tendon is inserted into the bone. The digital channel, in the portion included in zone II, is strengthened in proximal-distal direction from the pulleys in ring fingers (A1, A2, A3) and from the cruciform pulleys (C1 and C2). It also contains the deep flexor tendon (DFT) and the two slips of insertion of the superficial flexor tendon (SFT) (2). Due to the narrowness and rigidity of the digital channel in this zone and the large volume of structures it contains, it is clear that the physiological gliding of tendons in this zone is subject to a delicate equilibrium.

For these reasons, both the physiological process and surgical trauma involving skeletal, ligamentous and tendinous structures, interferes with tendon gliding, and can cause serious functional impairment. In fact, surgical treatment of zone II of the hand is burdened by a high incidence of failures: it is estimated that around 10% of tenolysis and tendon repair interventions fail due to breakage or lockage of the tendon due to development of adhesions in surrounding tissue (3). In order to address this problem, several anti-adhesion strategies have been attempted including:

- The use of revolving tenolysis surgery, which nevertheless leads to a persistent inflammatory response, determining the development of more tenacious and larger adhesions that can eventually result in complete functional loss.
- The use of gliding flaps, including a reverse forearm radial fascial flap. Even if often effective, the patient must undergo a high-risk surgical procedure the possibility of both local and systemic complications (4-6).
- The intra-surgical application of barriers, which even if generally effective, are plagued by collateral effects and adequate long-term results (7, 8).

Additionally, the restoration of peritendinous sliding surfaces after trauma is considered to be one of the principal motivations of hand surgery; surgical adhesions, by preventing proper tendon

gliding, especially in zone II, are the primary cause of failure of tenorrhaphy and tendon transplantation (9).

Recent preclinical studies have evaluated the anti-adhesion properties of a hyaluronan-based gel, namely Hyaloglide®. This gel possesses several characteristics that render it potentially useful as an anti-adhesive device including its natural lubricant and visco-elastic properties, allowing it to remain in the surgical field time long enough to prevent the development of peritendon adhesions. These features, moreover, are not present in native hyaluronic acid (10-13).

While numerous surgical experiences have been reported, it is difficult to compare different results due to the lack of uniform methods for evaluation of surgical results. To overcome this problem, we have assessed a standardized protocol to evaluate the outcome of surgical intervention in zone II of the hand. In order to verify the validity of this protocol, we have used it to evaluate the efficacy of the antiadherence device Hyaloglide.

MATERIALS AND METHODS

In order to obtain consistent results, we relied upon a group of hand surgeons of the Italian Society of Hand Surgery (SICM), which also increased the possibility of recruiting a larger number of patients. The recruitment process was randomized and rigid criteria were applied so that the sample population would be as homogeneous as possible. All pre-, intra- and post-surgical procedures were also clearly encoded to minimize variability among the operators.

Study design (Fig. 1): this was a multicenter, controlled, and randomized study performed under the auspices of the SICM. Thirteen centers were involved in the study and a minimum of 4 patients for each center were planned for recruitment; patients were randomized using the sealed-envelope technique into two groups: the Hyaloglide-treated group and a control group, as exemplified in the following flow chart. A total of 52 patients were enlisted.

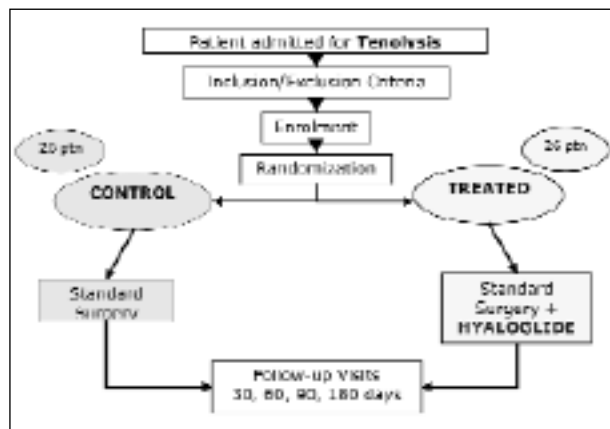


Figure 1. Study flow chart

Inclusion/exclusion criteria: patients undergoing tenolysis that met the criteria in table 1 were eligible to participate in the study.

Experimental methods: All pre-, intra-, and post-operative procedures were standardized and accurately described in order to reduce the variability among the various centers and surgeons as much as possible. Following surgical treatment for tenolysis, patients were submitted to follow-up visits at 30, 60, 90, and 180 days at which time data regarding compliance, functional impact, and efficacy were collected. A discretionary visit was also possible at 360 days.

Data evaluation: the following criteria of socio-healthcare impact were assessed:

- The reduced version of the disability of the arm, shoulder and hand questionnaire (Quick

DASH) that evaluates the quality of the life was administered at surgery for tenolysis at 30 and 180 days. (14);

- Number of interventions for tenolysis within the 180 day follow-up period;
- Time interval between surgical treatment and return to work;
- Job days lost before surgery and after return to work.

Effectiveness and tolerability were evaluated at all follow-up visits using the criteria listed below:

- Total active motion (TAM) according to Strickland’s criteria. This test allows for assessment of active finger function by comparison to the controlateral digit, calculated as a percentage. Strickland defines the results as excellent if a percentage of 85-100% is obtained, good from 70-84%, satisfactory from 50-69%, and as poor when the percentage is less than 50% (15).
- Visual assessment of finger reflexes.
- All adverse events (AE), defined as any unfavorable episode, were recorded.

RESULTS

Conclusive data, related to 49 patients enlisted, has been analyzed using the statistic method LOCF (Last Observation Carried Forward). Of these, 45 patients (19 control and 26 treated) have

Table 2. Inclusion/exclusion criteria for patients undergoing tenolysis

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> • Flexor tendon adhesion in zone II of fingers • Single digit adhesions • Adhesions present for 3 months or longer • Age between 18-65 years • Written informed consent 	<ul style="list-style-type: none"> • Adhesions of zones I, III, IV and V • Adhesions of thumb • Adhesions present for less than 3 months • Extensor tendon adhesions, joint stiffness • Adhesions and lesions of principal peripheral nerves • Tendon grafts • Associated bone treatments • Cutaneous tissue loss that requires grafts or flaps • Pregnancy • Diabetes Mellitus, collagen and immune diseases, neoplasia, blood clotting disease, psychiatric diseases • Smokers

concluded the follow-up. As indicated in the figures 2-6, in patients treated for tenolysis, the TAM was improved by 160% in the group of patients treated with Hyaloglide® compared to the control group and the treated group lost 20 day of work less then the control group.

There were no clinically relevant adverse events.

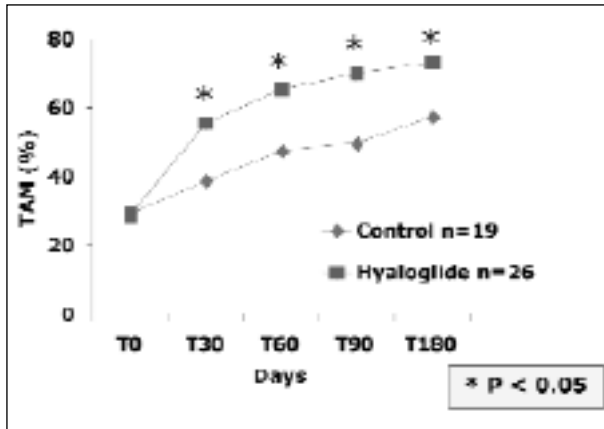


Figure 2. Total active of motion - TAM (%) (15).

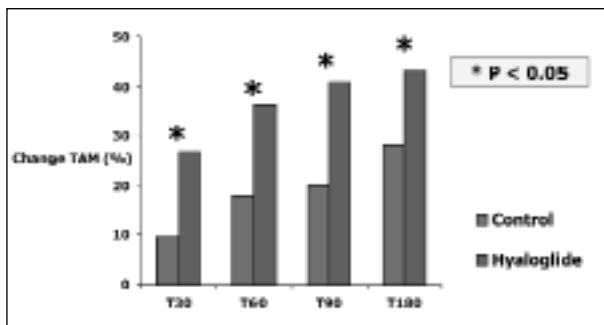


Figure 3. TAM - Change from baseline.

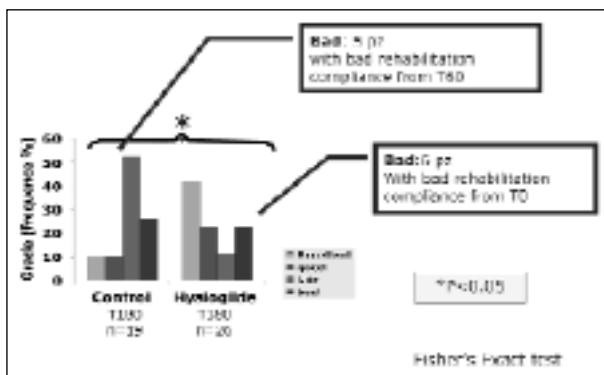


Figure 4. TAM - Grade.

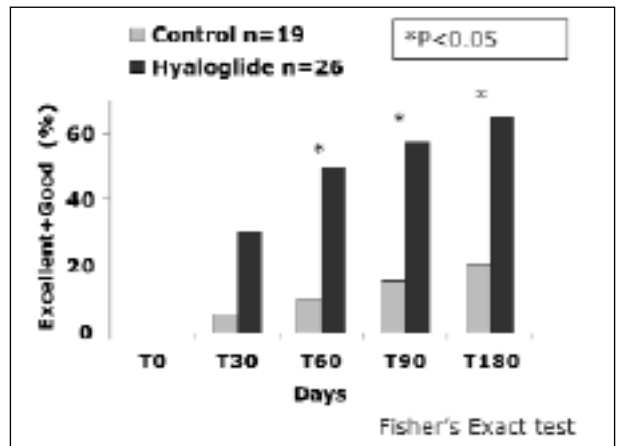


Figure 5. TAM - Grade.

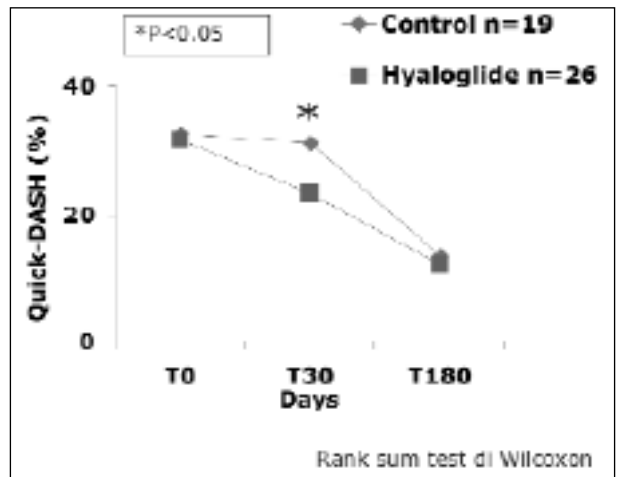


Figure 6. TAM - Grade.

CONCLUSIONS

Due to the multicentric nature of this study, we have already succeeded in enrolling 56 patients. Our results demonstrate that the study protocol provides excellent assessment of efficacy and tolerability outcome measures. Moreover, the large number of patients enrolled, the rigorous inclusion/exclusion criteria, combined with the descriptive accuracy of all surgical and therapeutic procedures, has provided a particularly homogeneous sample population. In patients treated for tenolysis, the TAM was improved by 160% in the group of patients treated with Hyaloglide® compared to the control group. The analysis of a larger patients

cohort will likely allow for statistically significant differences that would definitively demonstrate the efficacy of Hyaloglide® in the prevention of surgical adhesions following tenolysis.

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